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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/373,018 | 08/11/99 | NASH | H 10845/014002 |

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EXAMINER
MORAN, M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631 | 13 |

DATE MAILED: 02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/373,018

Applicant(s)

NASH ET AL.

Examiner

Marjorie Moran

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-22 and 51-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 16-22, 51-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1631.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 16-22 and 51-53, drawn to a method of identifying a ligand to a first biomolecule, classified in class 435, subclass 7.1.
- II. Claims 54-63, drawn to a method of identifying a ligand to a second biomolecule, classified in class 435, subclass 7.1.
- III. Claims 64-67, drawn to a method of identifying a ligand for a first biomolecule which is not a ligand for a second biomolecule, classified in class 435, subclass 7.1.
- IV. Claims 68-72, drawn to a method of identifying compounds which bind to defined sites on a biomolecule, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Invention I is distinct from Invention II as steps required for Group II require use of different products and are directed to a different result than are the steps for Group I. In addition, the method of Group I can be practiced independently from and without regard to the steps of Group II. Although Group II is related to Group I as the method of

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Group II incorporates some of the steps of Group I, the Groups are distinct for the reasons set forth above.

Group I is not related to either of Groups III or IV. Each of Groups III and IV recite use of different products and different method steps than does the method of Group I, and each is directed to a different result than the method of Group I. For these reasons, Group I is separate and distinct from either of Groups III or IV.

Group II, III, and IV are unrelated. Each of Groups II, III and IV recite different method steps and may be practiced without knowledge of or regard to any of the other methods. For these reasons, each of Groups II, III, and IV is separate and distinct.

Because these inventions are distinct for the reasons given above and the search required for Groups II, III, and IV is not required for Group I, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Group I, above, is elected, applicant must also elect a biomolecule from the following (a) a nucleic acid and (b) a protein.

If Group II, above, is elected, applicant must also elect a first and second biomolecule (each) from the following: (a) a nucleic acid; (b) a protein. If (b) is selected, applicant must further elect from the following for a second biomolecule (b1) a protein which is NOT a derivative of a first protein; (b2) a protein which is a derivative of a first protein; (b3) a protein which has a different post-translational modification from a first protein; or (b4) a protein which is a complex of the first protein and a ligand.

If group III, above, is elected, applicant must also elect a first and second biomolecule (each) from the following: (a) a nucleic acid; (b) a protein.

If Group IV, above, is elected, applicant must also elect a biomolecule from the following: (a) a nucleic acid, or (b) a protein AND must elect a second ligand from the following: (a) a nucleic acid; (b) a protein; or (c) a cofactor.

Claims 16, 54, 64, and 68 are generic to a plurality of disclosed patentably distinct species comprising various scaffold precursors and peripheral moiety precursors. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. For any of Groups I-IV elected, above, applicant must also elect one of the disclosed species of scaffold precursor AND one of the disclosed species of reactive groups AND one of the disclosed species of peripheral moiety precursor. The scaffold precursors include cyclic hydrocarbon or heterocyclic groups, reactive-group substituted benzene, biphenyl, cyclohexane, bipyridyl, N-phenylpyrrole, diphenyl ether, naphthalene, benzophenone (all disclosed on page 14 of the specification), and the structures disclosed on page 15 of the specification. Different reactive groups are disclosed in various places throughout the specification; specific combination of reactive groups and scaffold precursors are disclosed on page 18 of the specification. Peripheral moiety precursors include amino acid side chains, nucleotide bases, nucleotide base "analogs", sugar moieties, sulfonamides, peptidomimetic groups, charged groups, polar groups, alkyl groups, aryl groups (all disclosed on page 16), and various other groups as taught on page 19 of the specification. Applicant should note that an elected combination of scaffold, reactive

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group and peripheral moiety must be both enabled and fully supported by the originally filed specification. Examples of particular combinations of scaffold, reactive groups, and peripheral moieties are disclosed on pages 20-22 of the specification.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is required under 35 U.S.C. 121 to elect a single Group from among Groups I-IV above AND to elect a first biomolecule (if Group I is elected) or a first and second biomolecule and/or ligand (if any of Groups II-IV are elected) AND to elect a scaffold precursor, reactive group and peripheral moiety precursor from the disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 16, 54, 64, and 68 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

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all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant's arguments regarding the "impossibility" of election of a single compound species, as set forth in the response filed 11/6/00 have been fully considered. In response, it is noted that the new restriction requirement, as set forth above, does not require election of a single compound species, but requires election of a scaffold precursor, reactive group, and peripheral moiety precursor, such that the resulting combination represents a group of compounds with a common "backbone" structure. As set forth above, the specification describes several specific combinations of scaffold, reactive and peripheral moiety groups on pages 20-22. As the instant specification teaches that such combinations are suitable for use in the claimed method (pages 18-20), the examiner maintains that such an election would not be "impossible".

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524.



Marjorie A. Moran
February 8, 2001



MARY K. ZEMAN
PATENT EXAMINER
A.U. 1631